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SERIAL NO.: 07/256,689
FILING DATE: 10/12/88
APPLICANT: CHARLES T. CASKEY ET AL.
TITLE: MULTIPLEX GENOMIC DNA
AMPLIFICATION FOR DELETION
DETECTION

§ D-5050
§ GR. ART. UNIT 182
§ Examiner:
§ A. Marschel
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Hon. Commissioner of Patents
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20231, on July 26, 1990
Thomas D. Paul
Name of applicant, assignor, or
Registered Representative

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Int. Clerk 7/26/90
Date

1. Preliminary Statements

Applicants submit herewith material of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. While this information disclosure statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, or other information referred to therein is "prior art", for this invention unless specifically designated as such. In accordance with 37 CFR 1.97(b), the filing of this information disclosure statement shall not be construed to mean that a search has been made or that no material information as defined in 37 CFR 1.56(a) exists.

2. Time of filing

This information disclosure statement is filed prior to receipt of any office action in this application.

3. Listing of information

A list of the material is set forth on the attached Form PTO-1449 (modified).

4. Copies of listed information items accompanying this statement

A copy of each of the items on PTO-1449 (modified) is supplied herewith.

5. Concise explanation of listed information items


A concise explanation of each item listed on PTO-1449 (modified) is given below:

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Other:

A. Farzadegan, H.; Polis, M. A.; Wolinsky, S. M.; Rinaldo, C. R. Jr.; Sninsky, J. J.; Kwok, S.; Griffith, R. L.; Kaslow, R. A.; Phair, J. P.; Polk, B. F.; Saah, A. J.; "Loss of Human Immunodeficiency Virus Type 1 (HIV-1) Antibodies with Evidence of Viral Infection in Asymptomatic Homosexual Men: A Report from the Multicenter AIDS Cohort Study", Ann-Intern-Med. 108:6, June 1988, pp. 785-790.

B. Laure, F.; Courgnaud, V.; Rouzioux, C.; Blanche, S.; Veber, F.; Burgard, M.; Jacomet, C.; Griscelli, C.; Brechot, C.; "Detection of HIV 1 DNA in Infants and Children by Means of the Polymerase Chain Reaction", Lancet 2 (8610), 1988, pp. 538-541.

C. Newton, C. R.; Kalsheker, N.; Graham, A.; Powell, S.; Gammack, A.; Riley, J.; Markham, A. F.; "Diagnosis of Alpha-1 Antitrypsin Deficiency by Enzymatic Amplification of Human Genomic DNA and Direct Sequencing of Polymerase Chain Reaction Products, Nucleic Acids Res. 16 (17), 1988, pp. 8233-8244. Demonstrates that two separate sequences could be simultaneously amplified in a ^{PCR} ~~PCR~~ reaction and describes the technique of sequencing PCR products to identify point notations leading to genetic disease. 

D. Kawasaki, E. S.; Clark, S. S.; Coyne, M. Y.; Smith, S. D.; Champlin, R.; Witte, O. N.; McCormick, F. P.; "Diagnosis of Chronic Myeloid and Acute Lymphocytic Leukemias by Detection of Leukemia-Specific Messenger RNA Sequences Amplified In-Vitro", Proc. Natl Acad Sci U S A 85 (15), 1988, pp. 5698-5702.

E. Li, H.; Gyllensten, U. B.; Cui, X.; Saiki, R. K.; Erlich, H. A.; Arnheim, N.; "Amplification and Analysis of DNA Sequences in Single Human Sperm and Diploid Cells", Nature (Lond) 335 (6189), 1988, pp. 414-417. Demonstrates that PCR can be used to simultaneously amplify two sequences from a single cell. However, the authors were unable to achieve total simultaneous amplification of both sequences. Instead, they preamplified using two primer

sets, and then split the reaction in half. Each half was then subsequently amplified with one or the other primer sets to separately amplify the two target regions.

F. Duggan, D. B.; Ehrlich, G. D.; Davey, F. P.; Kwok, S.; Sninsky, J.; Goldberg, J.; Baltrucki, L.; Poiesz, B. J.; "HTLV-I-Induced Lymphoma Mimicking Hodgkin's Disease. Diagnosis by Polymerase Chain Reaction Amplification of Specific HTLV-I Sequences in Tumor DNA", Blood 71 (4), 1988, pp. 1027-1032.

G. Murakawa, G. J.; Zaia, J. A.; Spallone, P. A.; Stephens, D. A.; Kaplan, B. E.; Wallace, R. B.; Rossi, J. J.; "Direct Detection of HIV-1 RNA from AIDS and ARC Patient Samples", DNA (N Y) 7 (4), 1988, pp. 287-295.

H. Byrne, B. C.; Li, J. J.; Sninsky, J.; Poiesz, B. J.; "Detection of HIV-1 RNA Sequences by In-Vitro DNA Amplification", Nucleic Acids Res. 16 (9), 1988, p. 4165.

I. Cai, S. P.; Zhang, J-Z.; Huang, D-H.; Wang, Z-X., Kan, Y. W.; "A Simple Approach to Prenatal Diagnosis of Beta Thalassemia in a Geographic Area Where Multiple Mutations Occur", Blood 71 (5), 1988, pp. 1357-1360.

J. Dilella, A. G.; Huang, W. M.; Woo, S. L. C.; "Screening for Phenylketonuria Mutations by DNA Amplification with the Polymerase Chain Reaction", Lancet 1 (8584), 1988, pp. 497-499.

K. Higuchi, R.; Von Beroldingen, C. H.; Sensabaugh, G. F.; Erlich, H. A.; "DNA Typing from Single Hairs", Nature (Lond) 332 (6164), 1988, pp. 543-546.

L. Ou, C-Y.; Kwok, S.; Mitchell, S. W.; Mack, D. H.; Sninsky, J. J.; Krebs, J. W.; Feorino, P.; Warfield, D.; Schochetman, G.; "DNA Amplification for Direct Detection of HIV-1 in DNA of Peripheral Blood Mononuclear Cells", Science (Wash D C) 239 (4837), 1988, pp. 295-297.

M. Saiki, R. K.; Gelfand, D. H.; Stoffel, S.; Scharf, S. J.; Higuchi, R.; Horn, G. T.; Mullis, K. B.; Erlich, H. A.; "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase", Science (Wash D C) 239 (4839), 1988, pp. 487-491.

N. Scharf, S. J.; Horn, G. T.; Erlich, H. A.; "Direct Cloning and Sequence Analysis of Enzymatically Amplified Genomic Sequences", Science (Wash D C) 233 (4768), 1986, pp. 1076-1078.

O. Impriam, C. C.; Saiki, R. K.; Erlich, H. A.; Teplitz, R. L.; "Analysis of DNA Extracted from Formalin-Fixed, Paraffin-Embedded Tissues by Enzymatic Amplification and Hybridization with Sequence-Specific Oligonucleotides", Biochem Biophys Res Commun 142 (3), 1987, pp. 710-716.

P. Erlich, H. A.; Horn, G. T.; Saiki, R. K.; Scharf, S. J.; Mullis, K. B.; Bugawan, T.; "Genetic Analysis Using Enzymatic Amplification of Specific Genomic Sequences", Lerman, L. S. (Ed.). Current Communications in Molecular Biology: DNA Probes: Applications in Genetic and Infectious Disease and Cancer; Conference, Cold Spring Harbor, N.Y.; USA, Apr. 20-23, 1986. X+188P. Cold Spring Harbor Laboratory: Cold Spring Harbor, N.Y., USA. Illus Paper ISBN 0-87969-196-4, 1986, pp. 107-112.

Q. Wong, C.; Dowling, C. E.; Saiki, R. K.; Higuchi, R. G.; Erlich, H. A.; Kazazian, H. H. Jr.; "Characterization of Beta-Thalassemia Mutations Using Direct Genomic Sequencing of Amplified Single Copy DNA", Nature (Lond) 330 (6146), 1987, pp. 384-386.

R. Mullis, K.; Faloona, F.; Scharf, S.; Saiki, R.; Horn, G.; Erlich, H.; "Specific Enzymatic Amplification of DNA In-Vitro: The Polymerase Chain Reaction", Cold Spring Harbor Laboratory, Cold Spring Harbor Symposia on Quantitative Biology, Vol. 51, (Parts 1 and 2), Molecular Biology of Homo Sapiens; June 1986, XXV+702P, (Part 1);

XV+527P. (Part 2). Cold Spring Harbor Laboratory: Cold Spring Harbor, New York, USA. Illus. ISBN 0-87969-053-4 (Paper); ISBN 0-87969-052-6 (Cloth). 0 (0), pp. 263-273.

S. Saiki, R. K.; Bogawan, T. L.; Horn, G. T.; Mullis, K. B.; Erlich, H. A.; "Analysis of Enzymatically Amplified B-globin and HLA-DQ α -DNA with Allele-Specific Oligonucleotide Probes", Nature (London) 324, 1986, p. 163-166.

T. Kogan, S. C.; Doherty, M.; Gitschier, J.; "An Improved Method for Prenatal Diagnosis of Genetic Diseases by Analysis of Amplified DNA Sequences", N. Engl. J. Med. 317, 1987, p. 985-990.

U. Saiki, R. K.; Chang, C-A.; Levenson, C. H.; Warren, T. C.; Boehm, C. D.; Kazazian, H. H. Jr.; Erlich, H. A.; "Diagnosis of Sickle Cell Anemia and B Thalassemia With Enzymatically Amplified DNA and Non-Radioactive Allele-Specific Oligonucleotide Probes", N. Engl. J. Med. 319, 1988, p. 537-541.

V. Chelly, J.; Kaplan, J-C.; Maire, P.; Gautron, S.; Kahn, A.; "Transcription of the Dystrophin Gene in Muscle and Non-Muscle Tissues", Nature (London) 333, 1988, p. 858-860.

W. Darras, B. T.; Koenig, M.; Kunkel, L. M.; Francke, U.; "Direct Method for Prenatal Diagnosis and Carrier Detection in Duchenne/Becker Muscular Dystrophy using the Entire Dystrophin cDNA", Am. J. Med. Genet. 29, 1988, p. 713726.

X. Hejtmancik, J. F.; Harris, S. G.; Tsao, C. C.; Ward, P. A.; Caskey, C. T.; "Carrier Diagnosis of Duchenne Muscular Dystrophy Using Restriction Fragment Length Polymorphisms", Neurology 36, 1986, p. 1553-1562.

Y. Kunkel, L. M.; and co-authors; "Analysis of Deletions in DNA from Patients with Becker and Duchenne Muscular Dystrophy", Nature (London) 322, 1986, p. 73-77.

Z. Heilig, R.; Lemaire, C.; Mandel, J-L.; "A 230kb Cosmid Walk in the Duchenne Muscular Dystrophy Gene: Detection of a Conserved Sequence and of a Possible Deletion Prone Region", Nucl. Acids Res 15(22), 1987, p. 9129-9142.

AA. Koenig, M.; Hoffman, E. P.; Bertelson, C. J.; Monaco, A. P.; Feener, C. C.; Kunkel, L. M.; "Complete Cloning of the Duchenne Muscular Dystrophy (DMD) cDNA and Preliminary Genomic Organization of the DMD Gene in Normal and Affected Individuals", Cell 50. 1987, p. 509-517.

BB. Koenig, M.; Monaco, A. P.; Kunkel, L. M.; "The Complete Sequence of Dystrophin Predicts a Rod-Shaped Cytoskeletal Protein", Cell 53. 1988, p. 219-288.

CC. Chamberlain, J. S.; Pearlman, J. A.; Muzny, D. M.; Gibbs, R. A.; Ranier, J. E.; Reeves, A. A.; Caskey, C. T.; "Expression of the Murine Duchenne Muscular Dystrophy Gene in Muscle and Brain, Science 239, 1988, p. 1416-1418.

DD. Chamberlain, J. S.; Ranier, J. E.; Pearlman, J. A. Farwell, N. J.; Gibbs, R. A.; Nguyen, P.; Muzny, D. M.; Caskey, C. T.; "Analysis of Duchenne Muscular Dystrophy Gene Mutations in Mice and Humans, Cellular and Molecular Biology of Muscle Development, UCLA Symposia on Cellular and Molecular Biology, New Series, Vol. 93 (Stockdale, F. and Kedes, L., eds), New York, Alan R. Liss Press. 1989 p. 951-962.

EE. Chamberlain, J. S.; Gibbs, R. A.; Ranier, J. E.; Nguyen, P. N., Caskey, C. T.; "Deletion Screening of the Duchenne Muscular Dystrophy Locus Via Multiplex DNA Amplification", Nucleic Acids Res. 16(23), 1988, p. 11141-11156.

FF. Jeffrey, A. J.; Wilson, V.; Neumann, R.; Keyte, J.; "Amplification of Human Minisatellites by the Polymerase Chain Reaction: Towards DNA Fingerprinting of Single Cells", Nucleic Acids Res. 16(23), 1988, p. 10953-10971.

GG. Chehab, F.F.; Doherty, M.; Cai, S.; Kan, Y.W.; Cooper, S.; Rubin, E. M.; "Detection of Sickle Cell Anaemia and Thalassaemias", Nature 329:293, 1987.

HH. Chamberlain, J. S.; Pearlman, J. A.; Gibbs, R. A.; Ranier, J. E.; Farwell, N. J.; Caskey, C. T.; "Expression of the Murine Duchenne Muscular Dystrophy Gene in the Muscle and Brain of Normal and Mutant MDX Mice", ~~Molecular Biology of Human Muscle Disease~~, M040. *J. Cell Biochem.* 12C:319, 1988

A., B., D., F., G., H., K., L., M., N., O., P., Q., R., T., U., X., Y. and Z. are general background articles describing the procedure and use of PCR.

(I) (J) (S) General background. The authors describe the PCR amplification of multiple regions of a gene, amplifying a single region of the gene in each reaction. Mutations were screened for by dot-blot hybridization with Allele-specific oligonucleotide probes.

6. Person making this information disclosure statement.

The person making this statement is the inventor signed below.



Jeffrey S. Chamberlain